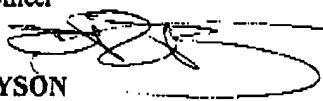


**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2093636/JMS/TDO/LMa	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No.  <b>PCT/AU 98/00723</b>	International filing date (day/month/year)  4 September 1998	Priority Date (day/month/year)  5 September 1997
International Patent Classification (IPC) or national classification and IPC  Int. Cl. <sup>6</sup> G01N 33/68		
Applicant  THE FLINDERS UNIVERSITY OF SOUTH AUSTRALIA et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.																								
2.	<p>This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of      sheet(s).</p>																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 5%;">I</td> <td style="width: 5%;"><input checked="" type="checkbox"/></td> <td>Basis of the report</td> </tr> <tr> <td>II</td> <td><input type="checkbox"/></td> <td>Priority</td> </tr> <tr> <td>III</td> <td><input type="checkbox"/></td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>IV</td> <td><input type="checkbox"/></td> <td>Lack of unity of invention</td> </tr> <tr> <td>V</td> <td><input checked="" type="checkbox"/></td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td>VI</td> <td><input checked="" type="checkbox"/></td> <td>Certain documents cited</td> </tr> <tr> <td>VII</td> <td><input type="checkbox"/></td> <td>Certain defects in the international application</td> </tr> <tr> <td>VIII</td> <td><input type="checkbox"/></td> <td>Certain observations on the international application</td> </tr> </table>	I	<input checked="" type="checkbox"/>	Basis of the report	II	<input type="checkbox"/>	Priority	III	<input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	IV	<input type="checkbox"/>	Lack of unity of invention	V	<input checked="" type="checkbox"/>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	VI	<input checked="" type="checkbox"/>	Certain documents cited	VII	<input type="checkbox"/>	Certain defects in the international application	VIII	<input type="checkbox"/>	Certain observations on the international application
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VIII	<input type="checkbox"/>	Certain observations on the international application																							

Date of submission of the demand 5 February 1999	Date of completion of the report 7 July 1999
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. (02) 6285 3929	Authorized Officer   <b>ISOBEL TYSON</b> Telephone No. (02) 6283 2563

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU 98/00723

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed.
- ☐ the description,        pages , as originally filed,  
                              pages , filed with the demand,  
                              pages , filed with the letter of .
- ☐ the claims,            pages , as originally filed,  
                              pages , as amended (together with any statement) under Article 19,  
                              pages , filed with the demand,  
                              pages , filed with the letter of .
- ☐ the drawings,        pages , as originally filed,  
                              pages , filed with the demand,  
                              pages , filed with the letter of .
- ☐ the sequence listing part of the description:  
                              pages , as originally filed  
                              pages , filed with the demand  
                              pages , filed with the letter of

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description,        pages
- ☐ the claims,            Nos.
- ☐ the drawings,        sheets/fig

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims 6,11,13-36	YES
	Claims 1-5, 7-10,12	NO
Inventive step (IS)	Claims 6,11,13-35	YES
	Claims 1-5, 7-10,12,36	NO
Industrial applicability (IA)	Claims 1-36	YES
	Claims	NO

## 2. Citations and explanations (Rule 70.7)

NOVELTY(N) and INVENTIVE STEP(IS): Claims 1-5, 7-10, 12, 36JP 4009665 A

This document discloses a method of determining a lung disease marker protein in blood using SP-A antibodies. This document therefore anticipates the present invention of claims 1,5, and 7 which are thus considered not novel or inventive.

Japanese J. Thor. Dis., 33(I), Nov. 1995, pp 1219-25

This document discloses a correlation between SP-A levels and lung disease, in particular a rise in SP-A levels in sera. The present invention as claimed in claims 1-5, 7- 10 and 12 are therefore not novel or inventive.

Japanese J. Thor. Dis., 34 Supp., Dec. 1996, pp 181-85

This document discloses that measurement of SP-A and SP-D in sera can provide an easily identifiable and useful clinical marker for diagnosing lung disease.

Thus, claims 1-5,7-10 and 12 are not considered novel or inventive in light of this document.

Derwent Accession Number 94-00758/01

This document discloses the detection and assay of SP-D in sera, which is useful for improved diagnosis of lung disease. Thus, claims 1-5 are not novel or inventive in light of this document.

EP 511011, A1

This document discloses detecting and measuring SP-A in blood and correlating SP-A levels, or a lack thereof, to a risk of Respiratory Distress Syndrome.

Thus, claims 1-5and 7 are not novel or inventive in light of this document.

Am. J. Resp. & Crit. Care Med., 152(6 Pt. 1), Dec 1995, pp 1860-66

This document discloses a correlation between SP-D and lung disease, having first determined SP-D levels in sera and BAL fluids. This measurement of SP-D in sera is used as an easily identifiable and useful clinical marker for diagnosing lung diseases.

Thus, Claims 1-5, 7- 1 0 and 12 are not novel or inventive in light of this document.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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## VI. Certain documents cited

## 1. Certain published documents (Rule 70.10)

Application No.  
Patent No.Publication date  
(day/month/year)Filing date  
(day/month/year)Priority date ( valid claim)  
(day/month/year)

US 5670328

23 September 1997

7 March 1995

7 March 1995

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure  
(day/month/year)Date of written disclosure referring to  
non-written disclosure  
(day/month/year)

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of : Box V

Respiration, 62(2), 1995, pp 64-69

This document discloses determination of SP-A concentration in sera of patients with various lung diseases. This has led to SP-A being used as a marker for diagnosing lung diseases.

Thus, claims 1-5, 7-10 and 12 are not novel or inventive.

INVENTIVE STEP (IS): Claim 36

Claim 36 cannot be considered inventive, being as it is to a mere spatial arrangement of known integers with no working interrelationship.